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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,989	02/05/2004	Paul A. Iaizzo	P-8965.00	5392

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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER	
BERTRAM, ERIC D	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,989	IAIZZO ET AL.	
	Examiner	Art Unit	
	Eric D. Bertram	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-13,18,20-24 and 26-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9-13,18,20-24 and 26-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because there is poor line quality in the drawings and the numbers and reference characters are not plain and legible, as described in the accompanying Draftperson's Patent Drawing Review. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by King (4,282,886). King discloses a medical lead, which is in this case an epicardial lead 10 (Col. 2, Line 7), comprised of a lead body with a distal end (Col. 2, Line 45) and a

glue segment 16 (Col.2, Line 21), as shown in Figure 3. The glue segment is composed of a tissue adhesive designed to adhere to the exterior of the heart (Col.1, Line 51). In figure 3, King shows a guard disposed in proximity to the glue segment, which is foil 16a encapsulating the adhesive to protect it (Col. 2, Line 25). As such, the glue segment can be said to be a capsule of tissue adhesive. In figure 1, King shows the glue segment to be in an annular shape, and shows in figure 3 that the glue segment is also in a tubular shape.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 6, 10, 13, 18, 22-24, 27, 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. (6,718,212) in view of King. Parry et al. disclose a medical lead, which is in this case an epicardial lead 50 (Col. 8, Line 32), comprised of a lead body with a distal end (Col. 1, Line 10) and a glue segment (Col. 9, Line 54). The glue segment is composed of a tissue adhesive designed to adhere to the epicardium of the heart (Col.10, Line 16). As shown in figure 4, the glue segment 54 is formed in both an annular and a tubular shape and the lead is comprised of tip electrode 56. Furthermore, the glue segment 54 is shown to be disposed about the tip electrode 56 in figure 4. Parry et al. also describe a trocar 22 (catheter) having a lumen that enables the lead to be advanced therethrough and contact the heart (Col. 8, lines 29-32). Also disclosed is an implantable pacemaker 58 coupled to lead 50 (Col. 9, line 20) as shown in figure 3. Parry et al. do not disclose, however, that the glue segment comprises a capsule of tissue adhesive. Attention is directed to the secondary reference of King, that discloses foil 16a encapsulating the adhesive as a guard (see figure 3 and Col. 2, Line 25). As such, the glue segment can be said to be a capsule of tissue adhesive. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the lead of Parry et al. by adding the foil of King in order to create a capsule of tissue adhesive that is protected from harm.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Hammerslag (5,383,899). King discloses the applicant's basic inventive concept as described above with the exception of the use of n-butyl cyanoacrylate as the tissue adhesive. Column 5, line 14 of Hammerslag shows n-butyl cyanoacrylate to be a known tissue adhesive in the art. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Hammerslag to modify the tissue adhesive of King by using n-butyl cyanoacrylate in the glue segment in order to have an adhesive that hardens rapidly (Col. 5, line 35).

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Munch et al. (6,463,335). King discloses the applicant's basic inventive concept as described above with the exception of the use of fibrin glue as the tissue adhesive. Column 19, line 2 of Munch et al. shows fibrin-based glue to be a known tissue adhesive in the art. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Munch et al. to modify the tissue adhesive of King by using fibrin-based glue in the glue segment in order to obtain rapid immobilization of the electrode and allow for faster surgical procedures (Col.18, line 62).

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over King in view of Theeuwes et al. (6,726,920). King discloses the applicant's basic inventive concept as described above with the exception of the glue segment having dots of tissue adhesive. Column 20, line 50 of Theeuwes discloses using several adhesive spots 32 (see figure 2D) in order to adhere a lead to an organ surface. It would have been an obvious manner of design choice to have the glue segment of King formed of

"dots" or "spots," since such a modification is generally recognized as being within the level of ordinary skill in the art and offers no disclosed advantage over other arrangements.

11. Claims 11 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Williams et al. (6,516,230). Parry et al., as modified above, disclose the applicant's basic inventive concept as described above with the exception of the tip electrode being formed of a helix-coil. Column 3, line 5 of Williams discloses a tip electrode 16 (see Figure 3a) taking the form of a helix. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Williams to modify the tip electrode of Parry by forming it into a helix in order to provide a more secure connection of the electrode to tissue.

12. Claims 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of Makower et al. (US 6,602,241). Parry et al. disclose the applicant's basic invention, including a medical lead, which is in this case an epicardial lead 50 (Col. 8, Line 32), comprised of a lead body with a distal end (Col. 1, Line 10) and a glue segment (Col. 9, Line 54). The glue segment is composed of a tissue adhesive designed to adhere to the epicardium of the heart (Col.10, Line 16). As shown in figure 4, the lead has a tip electrode 56 and the glue segment 54 is disposed about the tip electrode. Parry et al. also describe a trocar 22 (catheter) having a lumen that enables the lead to be advanced therethrough and contact the heart (Col. 8, lines 29-32). Parry et al. does not disclose, however, that the glue segment could be disposed

within the tip electrode. Attention is directed to the secondary reference of Makower et al., that discloses a delivery catheter 12 wherein a tissue adhesive is introduced through the tip of the delivery catheter in order to anchor the catheter at the treatment site (see figures 2, 8 and 9, and Col. 13, line 63-Col. 14, line 15). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the lead of Parry et al. by adding a glue segment that is disposed within the tip electrode in order to deliver adhesive directly at the treatment site and prevent inadvertent movement of the electrode (Col. 14, line 15).

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Hammerslag (5,383,899). Parry et al, as modified above, disclose the applicant's basic inventive concept with the exception of the use of n-butyl cyanoacrylate as the tissue adhesive. Column 5, line 14 of Hammerslag shows n-butyl cyanoacrylate to be a known tissue adhesive in the art. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Hammerslag to modify the tissue adhesive of Parry et al. by using n-butyl cyanoacrylate in the glue segment in order to have an adhesive that hardens rapidly (Col. 5, line 35).

14. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Munch et al. (6,463,335). Parry et al., as modified above, disclose the applicant's basic inventive concept with the exception of the use of fibrin glue as the tissue adhesive. Column 19, line 2 of Munch shows fibrin-based glue to be a known tissue adhesive in the art. It would have been obvious to one

of ordinary skill in the art at the time of the applicant's invention from the teaching of Munch to modify the tissue adhesive of Parry et al. by using fibrin-based glue in the glue segment in order to obtain rapid immobilization of the electrode and allow for faster surgical procedures (Col.18, line 62).

15. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Theeuwes et al. (6,726,920). Parry et al., as modified above, disclose the applicant's basic inventive concept as described above with the exception of the glue segment having dots of tissue adhesive. Column 20, line 50 of Theeuwes discloses using several adhesive spots 32 (see figure 2D) in order to adhere a lead to an organ surface. It would have been an obvious manner of design choice to have the glue segment of Parry et al. formed of "dots" or "spots," since such a modification is generally recognized as being within the level of ordinary skill in the art and offers no disclosed advantage over other arrangements.

16. Claims 31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Sigg et al. (US 6,931,286). Parry et al., as modified above, discloses the applicant's basic inventive concept with the exception of the lead containing a lumen and the catheter including mapping electrodes. Column 7, line 9 of Sigg et al. describes introducing a fluid delivery device through the lumen of a lead body. Column 5, line 22 of Sigg et al. describes the use of a mapping catheter. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Sigg et al. to modify the system of Parry et al. by adding a lumen in the lead in order to apply the tissue adhesive to the application

site and to also include mapping electrodes in order to locate a desirable application site (Col. 5, line 21).

17. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Starksen (5,571,161). Parry et al., as modified above, disclose the applicant's basic inventive concept as described above with the exception of a catheter with a balloon disposed at the distal end. Attention is directed to Column 4, line 34 of Starksen, which discloses an inflatable balloon attached at the distal end of the catheter. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Starksen to modify the system of Parry et al. by adding a balloon to the distal end of the catheter in order to protect the distal end from injuring cardiac tissue when the catheter is introduced in the heart (Col. 4, lines 34-36).

18. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Igo et al. Parry et al., as modified above, disclose the applicant's basic inventive concept with the exception of the catheter having a suction capacity. Column 6, line 65 of Igo et al. disclose a passage 120 in the catheter that is to supply a vacuum to withdraw fluid. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention from the teaching of Igo et al. to modify the system of Parry et al. by adapting the catheter to apply suction to a tissue site in order to remove excess moisture from the site.

Response to Arguments

19. Applicant's arguments with respect to claims 1, 3-7, 9-13, 18, 20-24, and 26-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cahalan et al. (4,768,523) discloses a medical lead with a glue segment comprised of tissue adhesive at a distal end. Shchervinsky et al. (US 6,324,435) and Koike et al. (US 6,341,230) disclose a medical lead using tissue adhesive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Eric D. Bertram
Examiner
Art Unit 3766

EDB